

IN THE CLAIMS:

Please amend and add new claims as shown in the claim listing below, which replaces all previous claim listings.

1. (Currently Amended) An osteogenic paste composition effective for the induction of new bone growth in a primate human patient, comprising:
a resorbable paste carrier comprising a macromolecular carrier material;
an osteogenic factor comprising a bone morphogenic protein, wherein said bone morphogenic protein is effective to stimulate both osteoblasts and osteoclasts when administered to a human, and wherein said bone morphogenic protein is incorporated into said paste composition in such an amount as to stimulate the osteoclasts sufficiently to cause an increase in the rate of resorption of the macromolecular carrier material when the paste composition is implanted in the human; and selected from BMP 2, BMP 4, BMP 6 or BMP 7, a LIM mineralization protein, or a nucleotide sequence encoding said bone morphogenic protein or LIM mineralization protein; and
a porous particulate mineral in an amount of at least 20% by volume of the composition, said amount being effective to provide a scaffold for bone ingrowth as the resorbable paste carrier is resorbed.
2. (Original) The composition of claim 1 which further comprises demineralized bone matrix.
3. (Original) The composition of claim 2 wherein the ratio of demineralized bone matrix to resorbable carrier is between about 1:4 and about 3:2 by weight.
4. (Original) The composition of claim 2 wherein the composition comprises 5-45% by weight resorbable carrier.
5. (Original) The composition of claim 1 wherein the resorbable carrier is flowable at temperatures above the body temperature of the mammal, but transitions to a non-flowable mass at or slightly above said body temperature.

6. (Previously Amended) The composition of claim 1 wherein the mineral is selected from the group consisting of bone particles, bioglass, tricalcium phosphate, hydroxyapatite, corraline, hydroxyapatite, biocompatible ceramic and non-resorbable biocompatible organic polymer.

7. (Original) The composition of claim 1 wherein the mineral comprises tricalcium phosphate, biphasic calcium phosphate, or hydroxyapatite particles having an average particle diameter of about 0.050 to about 5.0 mm.

8. (Original) The composition of claim 1 wherein the mineral comprises mammalian bone particles having a particle size of about 0.050 to about 5.0 mm.

9. (Original) The composition of claim 1 wherein the mineral comprises cortical human bone particles having an average particle diameter of about 0.050 to about 5.0 mm.

10. (Canceled)

11. (Previously Amended) The composition of claim 1 further comprising one or more osteogenic enhancing factors selected from the group consisting of osteogenic progenitor cells, autographic bone marrow, allographic bone marrow, transforming growth factor-beta, fibroblast growth factor, platelet derived growth factor, insulin-like growth factor, microglobulin-beta, antibiotics, antifungal agents, wetting agents, glycerol, steroids and non-steroidal anti-inflammatory compounds.

12. (Original) The composition of claim 1 wherein the mineral constitutes about 20% to about 80% by volume of the composition.

13. (Currently Amended) An osteogenic implant material effective for the induction of new bone growth in a mammal, comprising:

a resorbable paste carrier comprising gelatin, the resorbable carrier formulated to be flowable at temperatures above the body temperature of the mammal, and to transition to a non-flowable mass at said body temperature;

demineralized bone matrix;

an osteogenic factor comprising a bone morphogenic protein, wherein said bone morphogenic protein is effective to stimulate both osteoblasts and osteoclasts when administered to a human, and wherein said bone morphogenic protein is incorporated into said paste composition in such an amount as to stimulate the osteoclasts sufficiently to cause an increase in the rate of resorption of the macromolecular carrier material when the paste composition is implanted in the human; and selected from BMP-2, BMP-4, BMP-6 or BMP-7, a LIM mineralization protein, or a nucleotide sequence encoding said bone morphogenic protein or LIM mineralization protein; and

a particulate mineral having an average particle size of about 0.050 to about 5.0 mm, said mineral constituting at least 20% by volume of said composition.

14. (Original) The composition of claim 13 wherein the mineral constitutes about 20% to about 80% by volume of the composition.

15. (Original) The composition of claim 13 wherein the mineral comprises human bone particles.

16. (Original) The composition of claim 13 wherein the mineral comprises non-human bone particles, said particles having been treated to reduce their immunogenicity in humans.

17. (Canceled)

18. (Original) A method for inducing bone growth in a primate, comprising implanting in the primate a composition according to claim 1, at a site at which bone growth is desired.

19. (Original) The method of claim 18, wherein the site is in the spine of the primate.

20. (Original) The method of claim 19, which is a spinal fusion.

21. (Original) The method of claim 20, wherein the spinal fusion is an interbody spinal fusion.

22. (Original) The method of claim 20, which is a posterolateral spinal fusion.

23. (Original) The method of claim 19, wherein the primate is a human.

24. (Original) The method of claim 20, wherein the fusion includes a fusion between transverse processes of adjacent vertebrae.

25. (Original) A method of performing a spinal fusion in a human, comprising implanting between adjacent vertebrae to be fused an effective amount of a composition according to claim 1.

26. (Original) The method of claim 25, wherein the composition is implanted in combination with a load bearing device.

27. (Currently Amended) A method for inducing bone growth in a primate, comprising:

heating an effective amount of an osteogenic paste composition to a temperature at which it is flowable, said osteogenic implant material comprising a resorbable paste carrier that is flowable at temperatures above the body temperature of the primate, but which transitions to a non-flowable mass at or slightly above said body temperature; an osteogenic factor that stimulates osteoblasts and osteoclasts when administered to a primate, and wherein said osteogenic factor is incorporated in said paste composition in such an amount as to stimulate the osteoclasts sufficiently to cause an increase in the rate

of resorption of the resorbable paste carrier when the paste composition is implanted in the primate; and; and, a particulate mineral effective to provide a scaffold for bone ingrowth as the resorbable carrier is resorbed, said mineral constituting at least 20% by volume of the paste composition;

implanting said osteogenic paste composition at a site of desired new bone formation; and

cooling the osteogenic paste composition to a temperature sufficient to transition the osteogenic paste composition to a non-flowable mass.

28. (Original) The method of claim 27 wherein the implant material further comprises demineralized bone matrix.

29. (Original) The method of claim 27 wherein the primate is a human.

30. (New) The composition of claim 1, wherein:
said macromolecular carrier molecule comprises collagen.

31. (New) The composition of claim 1, wherein:
said resorbable paste carrier comprises a macromolecular carrier component consisting essentially of collagen.

32. (New) The composition of claim 1, wherein:
said macromolecular carrier molecule comprises gelatin.

33. (New) The composition of claim 1, wherein:
said bone morphogenic protein comprises BMP-2.

34. (New) The composition of claim 33, wherein:
said BMP-2 comprises recombinant human BMP-2.

35. (New) The composition of claim 1, wherein:

said bone morphogenic protein comprises BMP-4 or BMP-7.

36. (New) The composition of claim 1, wherein:

said bone morphogenic protein comprises BMP-2; and

said porous particulate mineral comprises particulate bicalcium phosphate.

37. (New) The composition of claim 36, wherein:

said bicalcium phosphate has a tricalcium phosphate:hydroxyapatite weight ratio in the range of about 80:20 to about 90:10.

38. (New) The composition of claim 36, wherein said BMP-2 is recombinant human BMP-2, and wherein the recombinant human BMP-2 is incorporated into the paste composition at a weight ratio of about 1:100 to about 1:500 relative to the overall paste composition.

39. (New) The composition of claim 13, wherein:

said carrier comprises gelatin.

40. (New) The composition of claim 13, wherein:

said bone morphogenic protein comprises BMP-2.

41. (New) The composition of claim 40, wherein:

said BMP-2 comprises recombinant human BMP-2.

42. (New) The composition of claim 13, wherein:

said bone morphogenic protein comprises BMP-4 or BMP-7.

43. (New) The composition of claim 13, wherein:

said bone morphogenic protein comprises BMP-2; and

said porous particulate mineral comprises particulate bicalcium phosphate.

44. (New) The composition of claim 43, wherein:
said bicalcium phosphate has a tricalcium phosphate:hydroxyapatite weight ratio
in the range of about 80:20 to about 90:10.

45. (New) A method of performing a spinal fusion in a human, comprising
implanting between adjacent vertebrae to be fused an effective amount of a composition
according to claim 36.

46. (New) A method of performing a spinal fusion in a human subject,
comprising:
providing an osteogenic composition including a resorbable paste carrier
including a macromolecular carrier material, a bone morphogenic protein, and a
particulate mineral material, wherein said bone morphogenic protein is effective to
stimulate both osteoblasts and osteoclasts when administered to the human subject,
wherein said bone morphogenic protein is incorporated into said paste composition in
such an amount as to stimulate the osteoclasts sufficiently to cause an increase in the rate
of resorption of the macromolecular carrier material when the paste composition is
implanted in the human subject, and wherein said particulate mineral constitutes at least
20% by volume of the paste composition and is effective to provide a scaffold for bone
ingrowth as the resorbable carrier is resorbed, said scaffold effective to remain in the
human subject for a period of time sufficient for formation of osteoid in a volume in
which bone growth is desired; and

implanting said osteogenic paste composition in the human patient in an interbody
space between adjacent vertebrae or between transverse processes of adjacent vertebrae,
wherein said osteogenic paste composition induces bone formation in a volume between
the adjacent vertebrae and said particulate mineral provides a scaffold for bone ingrowth
that remains until osteoid has formed in the volume between the adjacent vertebrae that
will receive bone ingrowth for fusion of the adjacent vertebrae.

47. The method of claim 46, wherein:
said resorbable macromolecular carrier material comprises collagen.

48. The method of claim 47, wherein:

said bone morphogenic protein comprises human BMP-2.

49. The method of claim 48, wherein:

said particulate mineral material comprises biphasic calcium phosphate.

50. The method of claim 46, wherein said resorbable macromolecular material comprises gelatin, hyaluronic acid, carboxymethyl cellulose, or collagen.